CONCISE EXPLANATORY STATEMENT

WAC 296-20-03002

The purpose of this document is to respond to the oral and written comments received at the public hearing and during the comment period. There are no changes between the proposed rule language and the rule language that is being adopted.

Rule adoption date: July 18, 2006
Rule effective date: August 18, 2006

Reasons for Adopting the Rule:
The purpose of this rulemaking is to put into rule an existing medical coverage decision to not authorize the Charite III lumbar artificial disc for the care and treatment of injured workers and victims of crime. The Charite III disc, the only artificial disc approved by the Food and Drug Administration (FDA), was approved for marketing in 2004. Since that time, more than 133 serious adverse events have been reported to the FDA from its use**.**

Lumbar artificial disc replacement is intended to address pain due to degenerative disc disease. The department reviewed the best scientific evidence on artificial discs and made a noncoverage decision because there was not substantial scientific support and thus the device has not been proven to be safe and efficacious. Putting this noncoverage decision in rule will give the department more legal support if challenged about the noncoverage decision and ensure the safety of treatment provided to injured workers since the Charite III disc is a treatment option not proven by scientific evidence.

The public comment period for this rulemaking began February 28, 2006 and ended April 14, 2006. The public hearing was held on April 7, 2006 at 1:30pm at the Department of Labor & Industries.

Summary of Public Hearing
Three people attended the public hearing. A representative from Depuy Spine, the manufacturer of the Charite III disc testified in opposition to the proposed rule. Two other people, representing Medtronic, were present at the hearing but did not testify, nor did they indicate on the sign up sheet as to whether they were in support of or in opposition to the rule.

Summary of Written Comments
Three written comments were received during the public comment period. Depuy Spine's comments detailed its opposition to the rule. Medtronic comments applauded the department on limiting the rule to the Charite III disc, and Boeing also wrote in support of the proposed rule.

Detail of Comments and Department Response:

Comment Received: Boeing concurs with the department's proposal that lumbar artificial disc replacement with Charite lumbar artificial disc should not be authorized treatment for workers' compensation claims.

Department Response: The department agrees with this comment.

Comment Received: Medtronic applauds the department's decision to limit the applicability of the proposed rule to the Charite disc. At the time of the comment, Medtronic stated that it has several artificial discs in the investigational stage and asks that the department review each disc on its own merits.

Department Response: The department agrees with this testimony and may consider reviewing each disc on its own merits.

Comment Received: Depuy Spine states that an absence of conclusive evidence on a new technology should not be the basis of non-coverage.

Department Response: The department disagrees with this comment .The department reviews the best available scientific evidence to make coverage decisions. An absence of substantial scientific evidence related to efficacy led to the department's finding that the Charite III disc is unproven and therefore investigational and controversial. Recently, CMS also made a noncoverage decision for people over 60 based on the lack of scientific evidence. Blue Cross Blue Shield reviewed the Charite disc and came to the conclusion that "the evidence is insufficient to determine whether the use of artificial vertebral discs improves the net health outcome or whether they are as beneficial as any established alternative… Therefore, the use of artificial vertebral discs for degenerative disc disease does not meet the Technology Evaluation Center (TEC) criteria."

Comment Received: Depuy Spine stated that the Charite disc is safe for its intended use

Department Response: The department disagreed with this. The Charite disc was approved for marketing in October 2004. To date there are at least 133 adverse events reported to the Food and Drug Administration (FDA).

Examples of adverse events include:

- Migration of the artificial disc resulting in either removal of the disc or maintaining the disc, both followed by fusion;
- Pedicle fractures;
- Subsidence, a settling of the disc into the bone; and
- Nicking of an artery or vein.

*The surgical procedure for disc replacement involves an anterior approach for exposure for the spine. With this approach, complications of vessel injury can occur **and have the** potential to be life threatening (Santos, Polly et al. Disc arthroplasty: lessons learned from total joint arthroplasty. Apin JH 2004:4:182s-189s. On revision surgery , Santos et al., state, "Revisions surgery for a failed disc arthroplasty is life threatening. Dealing with the scarring around the great vessels is the main challenge Indeed, the location of vital vascular structures may make it altogether impossible to perform such anterior abdominal exposures." Other postoperative difficulties such as infection, persistent pain, instability, and osteolysis can occur.

Comment Received: Depuy Spine stated that the clinical evidence supports the Charite III artificial disc.

Department Response: The department disagreed with this comment. One randomized controlled trial on the Charite III was conducted as part of the FDA approval process. However, only case series data from the trial has been published. The data from one center of the multi-center trial indicated that VAS and Oswestry scores for disc replacement subjects decreased over time.

While promising, the data does not indicate whether patients showed statistically significant improvement of over the fusion control group.

The Charite disc has been in use for many years in Europe; however, only one randomized control trial (the FDA pre-market approval study) has been completed. Many significant methodological questions have been raised about this trial including its non-inferiority design, selected comparison technology, possible lack of prospective statistical plan and duration of 2 years for a device designed for munch longer wear or use. This trial was not designed to evaluate the purported benefits of the Charite disc (maintained motion an deduced risk of adjacent segment degeneration); it therefore remains unknown what benefit over current technology the Charite disc may provide.

The Charite disc has been in use in Europe for at least 17 years, Putzier, et.al. Eur Spine J. 2005, Oct 28 did a retrospective clinical-radiological study to evaluate the long-term outcome after artificial disc replacement was performed. Seventy-one patients were treated with 84 Charite discs. Fifty three patients were available for long-term follow-up of 17 years. Sixty percent of the subjects experienced spontaneous ankylosis after 17 years. Reoperation was necessary in 11% of the patients. Although no adjacent segment degeneration was observed in the functional implants (17%), these patients were significantly less satisfied than those with spontaneous ankylosis.

***(Santos, Polly et al. Disc arthroplasty: lessons learned from total joint arthroplasty Spin JH 2004:4:182S-189S.)**

Comment Received: Depuy Spine stated that the Charite disc may lower costs.

Department Response: The department disagreed with this comment. The Charite artificial disc was compared to lumbar fusion in the study submitted to the FDA for marketing approval, yet the cost of the procedure and the disc for the Charite disc is $35,000 to $45,000 and the cost of lumbar fusions average $23,000. Cost information for the Charite artificial disc can be found at:

- **Hochschuler, et.al. Issues to consider before having artificial disc surgery. Spine-health {website} Nov. 16, 2004 Available at www.spine-health.com/topics/surg/charite/charite03.html. Accessed March 3, 2006.**
- **Morrow T. Spinal disc technology seeks to replace body's engineering marvel. Manage Care Magazine. June 2005. Available at www.managedcaremag.com/archives/0506/0506.biotech.html. Accessed March 31, 2006.**